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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/636,079	08/06/2003	Janet K. Yamamoto	UF-152FWCD2	1433
23557	7590	06/16/2006	EXAMINER	
SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO BOX 142950 GAINESVILLE, FL 32614-2950			CHEN, STACY BROWN	
		ART UNIT	PAPER NUMBER	
			1648	

DATE MAILED: 06/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/636,079	YAMAMOTO, JANET K.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Stacy B. Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 12 May 2006.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 31-36,38-43 and 50-63 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 31-36,38-43 and 50-63 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 06 August 2003 is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. Applicant's after-final amendment filed May 12, 2006 is acknowledged and entered. Claims 31-36, 38-43 and 50-63 remain pending and under examination. In the final Office action of March 22, 2006, claims 31-36, 38-43 and 50-63 were indicated as allowable. Upon further consideration of the claimed invention, prosecution in this application is reopened in order that the following new rejection may be made.

2. The following rejections are either moot or withdrawn:

- The rejection of claims 37, 42 and 43 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2 and 4 of U.S. Patent No. 5,846,825, is moot with respect to cancelled claim 37, and withdrawn with respect to claims 42 and 43 in view of Applicant's filing of a terminal disclaimer, which has been accepted.
- The rejection of claim 37 under 35 U.S.C. 112, first paragraph, for failing to meet the enablement requirement (with respect to the deposit of certain FIV strains) is moot in view of the cancellation of claim 37.

#### ***Claim Rejections - 35 USC § 112***

3. (*New Rejection*) Claims 31-36, 38-43 and 50-63 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a vaccine composition that induces a protective immune response against two or more subtypes of FIV, comprising an effective amount of an FIV immunogen that minimally includes the FIV envelope glycoprotein,

does not reasonably provide enablement for a vaccine comprising FIV peptides, proteins, and partial viruses that do not include the FIV envelope glycoprotein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claims broadly encompass a vaccine composition that induces protection against FIV infection (of multiple subtypes), comprising an amount of any FIV immunogen. The immunogens include synthetic FIV peptides, natural or recombinant FIV proteins, fragments of said proteins, cell-free whole or partial FIV virus, and cells infected with FIV virus. Applicant's specification is enabling for embodiments that encompass the FIV envelope glycoprotein from each of the at least two different FIV subtypes. Embodiments that do not encompass the envelope glycoprotein from each of the at least two difference subtypes, are not enabled by the specification.

The nature of the invention is the protection of felines against FIV infection by administering a composition that comprises at least two immunogens from at least two FIV subtypes. The state of the art is that dual subtype vaccines against FIV are effective when using embodiments that include the envelope proteins of both subtypes (*AIDScience*, 2002, Vol. 2, No. 8, pages 1-8, of record). The level of one of skill in the art is high, evidenced by the present inventors and those of the cited literature. The level of predictability in the art is limited when considering the administration of any FIV immunogen to protect against FIV. The level of predictability in the art with regard to embodiments that include envelope protein (such as whole virus, partial virus with envelope, and infected cell lines) increases. The amount of direction provided by the specification is limited to vaccines that include the envelope proteins of two

subtypes. The working examples are drawn to infected cell lines that protect felines against FIV infection.

Given the breadth of the claims, the state of the art, the level of skill in the art, the level of predictability, the working examples, the direction provided by Applicant, and the nature of the invention, one of skill in the art would not be able to practice the full scope of the invention without undue experimentation. Since the only embodiments that have shown protective capabilities are those that include the envelope protein of two subtypes, one of skill in the art would now know how to vaccinate with embodiments that do not include the envelope protein of two subtypes.

Note that this rejection is over embodiments of the claims that were not previously patented in Applicant's other applications.

### ***Conclusion***

4. No claim is allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The

examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

*Stacy B. Chen 6/14/06*

Stacy B. Chen  
Primary Examiner  
June 14, 2006